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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,316	07/17/2003	Robert W. Childers	5766US BX2009T01727	3437

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EXAMINER	
CHAPMAN, GINGER T	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1 and 8-10 are amended; claims 1-61 are pending in the application, claims 27-61 are withdrawn from consideration as being drawn to a nonelected invention; claims 1-26 are examined on the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 4, 8-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini et al (US 4,269,708) in view of Stringer et al (US 6,960,322 B2).

5. With respect to claim 1, Bonomini discloses a system for providing dialysis comprising:

6. a patient fluid loop (A) including a first pump 13 and multiple patient lumens (fig. 1 at arrows leading to (A), 13 and leading from 15;

7. a second fluid loop (B) including a second pump 17 and a medical fluid regenerator 31 (c. 2, ll. 52-54; c. 5, ll. 31-35);

8. a membrane device 10 in fluid contact with and separating the patient fluid loop and the second fluid loop, the membrane device 10 allowing at least one selected component of the fluid in the patient fluid loop to transfer to the second fluid loop;

9. the second loop being closed except for the transfer of the selected component via the membrane device (fig. 1); and

10. a controller 39 that operates the first and second pumps to recirculate fluid in the patient loop and the second loop (c. 5, ll. 46-52).

11. Bonomini discloses the claimed invention except for a gas separator that separates gases from the second fluid loop. Bonomini, at column 5, lines 7-11, provides motivation for a separator that removes air, i.e. gas from the loop to prevent air, i.e. gas bubbles from being entrapped within the blood flow. Stringer, at column 5, line 8 and lines 14-17, provides motivation for a gas separator that removes air and other gases from the circuit during operation of the system. As best depicted in Figures 2B (51) 6 and 7, Stringer teaches a gas separator that separates gas from a second fluid loop 22 (fig. 1) that separates gases from the second fluid loop (col. 5, line 1, lines 44-50). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with a gas separator as taught by Stringer since Stringer states, at column 47-49 and column 9, lines 5-10, that the benefit of forming the system with this design is that the gas separator can be used to remove gases while delivering blood to the patient thereby providing a safer dialysis system.

12. With respect to claim 2, Bonomini discloses the membrane device 10 is a dialyzer (c. 4, l. 53; c. 3, ll. 44-45).

13. With respect to claim 4, Bonomini discloses the patient loop is closed except for the transfer of selected components via the membrane device (c. 5, ll. 64-65 and c. 6, ll. 12-14 and ll. 44-46).

14. With respect to claim 8, Bonomini discloses a gas separator 15 that removes gas from at least one of the loops (c. 5, ll. 9-11).

15. With respect to claim 9, Bonomini discloses the gas separator and the medical fluid regenerator are provided in a single device 50 (c. 5, ll. 63-65).

16. With respect to claim 13, Bonomini discloses wherein blood is circulated through the patient fluid loop (A) (c. 4, ll. 50-52; c. 5, ll. 1-5).

17. Claims 3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Marantz et al (US 3,669,880).

18. With respect to claim 3, Bonomini discloses the claimed invention except for expressly disclosing a pressure gradient exists across the membrane device. Marantz teaches a system for dialysis comprising patient and second fluid loops, pumps, medical fluid regenerator and membrane device; and teaches, at c. 4, ll. 39-40, that transfer takes place due to a pressure gradient that exists across the membrane device, as is generally recognized in dialysis systems, see also c. 4, ll. 3-4 and ll. 28-35). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the membrane device of Bonomini has a pressure gradient across the membrane as taught by Marantz since Marantz states, at c. 4, ll. 39-

40, that the effectiveness of the dialysis system is determined by the pressure gradient that exists across the membrane device, thereby providing a more effective dialysis system.

19. With respect to claim 5, Bonomini discloses the claimed invention except for a nanofilter which allows urea to pass from the patient fluid loop to the second fluid loop. Bonomini teaches filter 14, thus providing motivation for such, but remains silent as to particular structure. Marantz, at c. 3, ll. 67-74 to c. 4, ll. 1-2, teaches providing a filter membrane device 73 containing small molecular size holes which allows molecules such as urea to pass through the membrane into the second fluid loop while prevents the passage of blood cells and proteins. Thus the filter of Marantz performs the substantially identical function as the instant claimed nanofilter in the substantially identical manner and thus comprises a nanofilter for purposes of permitting urea to pass therethrough. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the filter of Marantz in the system of Bonomini since Marantz states, at c. 5, l. 67 to c. 6, l. 2, that this type of filter allows urea to pass from the patient fluid loop to the second fluid loop.

20. Careful review of the instant Specification, in particular at ¶¶ [0196 and 199] reveal no structure is disclosed in the instant Specification with respect to a nanofilter, the Specification merely recites a nanofilter, thus the filter of Marantz meets the filter as claimed.

21. With respect to claims 6 and 7, Bonomini discloses the claimed invention except for the medical fluid regenerator includes a uremic toxic sorbent as recited in claim 6; includes at least one of urease, zirconium phosphate, zirconium oxide, and carbon. Bonomini teaches the medical fluid regenerator 31 contains a sorbent material comprising carbon thus suggesting carbon as a uremic toxic sorbent and thus meeting the claims.

22. In the alternative, Marantz teaches a medical fluid regenerator 22 including a uremic toxin sorbent 25 (c. 4, ll. 49-51 and ll. 68-70) and includes at least one of urease 25 (c. 2, l. 18), zirconium phosphate (c. 2, l. 15, l. 23; c. 4, ll. 72-73), zirconium oxide (c. 5, l. 3) and carbon (c. 5, l. 2). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the regenerator of Bonomini with the sorbents as taught by Marantz since Marantz states, throughout the document, that these sorbents provide efficient removal of toxins from the patient.

23. Claims 10, 11 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Savitz et al (US 4,229,299).

24. With respect to claim 10, Bonomini discloses the claimed invention except for a gas vent that vents gases from the patient and second fluid loops. Bonomini teaches a gas separator to prevent gas and air bubbles from being entrapped in the fluid loops and returned in the patient's blood flow, thus providing motivation for such. Savitz teaches a dialysis system comprising a vent 154 to vent air from the fluid circuits. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with a vent as taught by Savitz since Savitz states, at c. 13, ll. 4-10, that this prevents the detrimental effects of gas in the dialysate solution to the health of the patient.

25. With respect to claim 11, Bonomini discloses the claimed invention except for a multi-analyte sensor that monitors a concentration of electrolytes in the medical fluid. Savitz teaches a multi-analyte sensor 105. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with a sensor as taught by Savitz since Savitz states, at c. 6, ll. 40-54, that the benefit of using a multi-analyte

sensor is that it permits monitoring of electrolytes in the dialysis fluid to insure the solution ahs the proper level of salinity and electrolyte characteristics so that vital components of the blood are not list in solution by ion diffusion, thereby providing a safer dialysis system.

26. With respect to claims 18 and 19, Bonomini discloses the claimed invention except for at least one of the loops includes an in-line fluid heater; said heater includes a radiant heater and a plate heater. Savitz teaches in-line 129 fluid heaters 103, 152; and teaches at c. 12, ll. 28-30 that the heaters selected may be of any suitable type for the purpose of maintaining the dialysate solution at ~ normal body temperature. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with heaters of any suitable type as taught by Savitz since Savitz states, at c. 6, ll. 10-15, that the benefit of such a modification is that it prevents undue cooling or heating of the blood in contact with the dialysate and to prevent hemolysis thereby providing a safer dialysis system.

27. Claims 12, 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Scott et al (US 4,765,907).

28. With respect to claim 12, Bonomini discloses the claimed invention except for peritoneal dialysis fluid is circulated through the patient fluid loop. Bonomini, at c. 3, ll. 43-45, teaches the system can be used for dialysis, which encompasses peritoneal dialysis and thus appears to be contemplated by Bonomini. As best depicted in Figures 2 and 5, Scott teaches a patient fluid loop 24, second fluid loop 40, medical fluid regenerator 26 wherein peritoneal dialysis fluid is circulated through the patient fluid loop as is known in peritoneal dialysis (c. 1, ll. 17-24; c. 5, l. 68; c. 8, ll. 23-26 and ll. 52-53 and ll. 57-58; c. 6, ll. 35-36). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that dialysis as

contemplated by Bonomini include peritoneal dialysis fluid circulated through the patient fluid loop as taught by Scott since Scott states, at c. 1, ll. 26-28 and c. 8, ll. 50-53, that the abdominal cavity is an ideal location for dialyzing of body fluid against body fluids within the patients body 9c. 2, ll. 28-31) and provides the patient with greater independence.

29. With respect to claim 15, Bonomini discloses the claimed invention except for a balance chamber that balances flow within the second fluid loop. Scott teaches a balance chamber 16 (c. 7, ll. 46-58) that balances flow within the second fluid loop (c. 6, ll. 40-50; fig. 4). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with a balancing chamber as taught by Scott since Scott states, at c. 7, ll. 47-58 and ll. 65-68, that the benefit of providing a balancing chamber is that it achieves regeneration of the spent dialysis fluid within the loops by permitting the fluid to be itself dialyzed i.e. balanced against fresh dialysis fluid so as to regenerate that fluid for further kidney function.

30. With respect to claim 25, Bonomini discloses the claimed invention except for a fluid concentrate container in fluid communication with at least one of the loops. Scott teaches a fluid concentrate container 26 in fluid communication with the patient and second fluid loops (c. 8, l. 25 and ll. 34-36; c. 9, ll. 45-52). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with a fluid concentrate container as taught by Scott since Scott states, at .c 7, ll. 45-58, that the benefit of providing such is that it provides the fresh dialysis fluid against which the spent fluid is balanced against.

31. Claims 14, 16-17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Roberts et al (US 5,944,684).

32. With respect to claims 14, 16-17 and 26, Bonomini discloses the claimed invention except for at least parts of the loops are provided in a disposable device (**claim 14**); a controller enables fluid flow to flow in opposite directions through the multiple patient lumens (**claim 16**); and a dual lumen catheter defines the multiple patient lumens (**claim 17**) and the controller operates the first pump to continuously pump fluid into and out of a patient (**claim 26**). Roberts teaches a dialysis system wherein parts of the loops are provided in a disposable device (c. 3, ll. 50-52 and ll. 61-62; c. 7, ll. 29-31), a controller (c. 8, ll. 2-5) enables fluid flow in opposite directions through the patient lumens (c. 8, ll. 7-9) and pumps fluid continuously into and out of a patient (c. 8, ll. 7-11); and a dual lumen catheter defines the multiple patient lumens (c. 8, ll. 7-8). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Bonomini with the components taught by Roberts for the benefits of automated systems that Roberts discloses.

33. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Krivitski et al (US 5,685,989).

34. With respect to claims 20-21, Roberts in view of Savitz discloses the claimed invention except for optical, fluid volume and capacitance sensors. Krivitski provides clear motivation for optical sensors at c. 2, ll. 11-12. Krivitski, at c. 4, ll. 24-27, teaches that optical, fluid volume and impedance, i.e. capacitance, sensors are known to measure change of characteristics of blood flow through dialysis loops. Therefore it would have been obvious to one having ordinary skill

in the art at the time the invention was made to select any of these known sensors to obtain the benefits of blood monitoring that Krivitski discloses thereby providing a safer dialysis system.

35. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Laroche et al (US 2005/0102028 A1).

36. With respect to claims 22 and 23, Roberts in view of Savitz discloses the claimed invention except for capacitance sensors. As best depicted in Figure 1, Laroche teaches capacitance sensors 18, 22 to measure pressure within a chamber and the chamber is a pump 14 chamber as recited in claim 23. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was to include capacitance sensors as taught by Larocke in the chambers and system of Roberts/ Savitz since Laroche teaches their suitability for use in dialysis and extra-corporeal blood circulation systems and capacitance sensors are known in the art to measure pressure within chambers and pressure within a chamber is proportionate to volume of fluids or gases within a chamber and therefore could be used to measure and monitor pressure and volume within a chamber.

37. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonomini in view of Stinger and further in view of Schal (US 4,267,040).

38. With respect to claim 24, Bonomini discloses the claimed invention except for an ultrafiltrate container in fluid communication with at least one of the loops. Schal teaches a system comprising a patient loop and second fluid loop (fig. 8), balancing chambers and an ultra-filtrate container 85 (c. 14, ll. 26-27; ll. 35-37, ll. 41-43). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of

Bonomini with an ultrafiltrate container as taught by Schal since Schal states, at c. 14, ll. 41-43, that this permits ultra-filtrate to be drawn off and sampled for control purposes.

Response to Arguments

39. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

40. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

41. Karoor et al (US 7,241,272 B2) teaches a gas separator is a second fluid loop.

42. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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